10/057 080

Cofc

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 on MARCH 31, 2006.

Jenna M. Morrison, Patent Attorney

CERTIFICATE OF CORRECTION
Docket No. USF-222XCT
Patent No.6,998,040

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Abdul Malik and James D. Hayes
Issued	:	February 14, 2006
Patent No.	:	6,998,040
For	:	Sol-Gel Open Tubular ODS Columns with Charged Inner Surface for Capillary Electrochromatography

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below are the column and line numbers where errors occurred in the patent. In the right-hand column are the page and line numbers in the application where the correct information appears.

Patent Reads:	**Application Reads:**
Column 7, line 14 :	Page 12, line 13:
" n-Octadecyidimethylmethoxysilane,"	-- n-Octadecyldimethylmethoxysilane,--
Column 7, line 14-15:	Page 12, line 13-14:
"Methyl-n-Octadecyidiethoxysilane,"	--Methyl-n-Octadecyldiethoxysilane,--

Patent Reads:	**Application Reads:**
Column 7, line 18:	Page 12, line 16:
"n-Ocyidi-isobutylmethoxysilane,"	--n-Ocyldi-isobutylmethoxysilane,--
Column 7, line 19:	Page 12, line 17:
"n-ctylmethyidimethoxysilane,"	--n-ctylmethyldimethoxysilane,--
Column 7, line 28-29:	Page 12, line 23-24:
"3-mercaptopropylmethyidimethoxysilane"	--3-mercaptopropylmethyldimethoxysilane--
Column 7, line 66-67:	Page 13, line 23-24:
"N-tetradecyidimethyl"	--N-tetradecyldimethyl--
Column 8, line 3:	Page 13, line 26-27:
"N-trimethoxysilylpropyl-N,N,N,-"	-- N-trimethoxysilylpropyl-N,N,N--
Column 8, line 14:	Page 14, line 4:
"n-Octadecyidimethylmethoxysilane,"	--n-Octadecyldimethylmethoxysilane,--
Column 8, line 28-29:	Page 14, line 14-15:
"3-mercaptopropylmethyidimethoxysilane,"	--3-mercaptopropylmethyldimethoxysilane,--
Column 8, line 31-33:	Page 14, line 17-19:
"3-mercaptopropylcyanopropydi-methoxysilane, 3 mercaptopropyl-octadecyidiethoxysilane,"	--3-mercaptopropylcyanopropyldi-methoxysilane, 3-mercaptopropyl-octadecyldiethoxysilane,--
Column 8, line 52:	Page 15, line 5:
"invention has a pi value"	--invention has a pI value--
Column 15, line 48:	Page 27, line 14-15:
"40% Tris-HCl"	--40% tmM Tris-HCl--

Patent Reads:	**Application Reads:**
Column 17, line 7:	Page 31, line 1:
"Took, P. et al."	--Tock, P. et al.--
Column 18, line 40:	Page 33, Scheme 2:
"N-Octadecyldimethy[3-"	--N-Octadecyldimethyl[3--
Column 20, line 6:	Examiner's Amendment of August 2, 2005, page 2:
"thereon."	--thereon, that permits effective controlling of electroosmotic flow in the column.--

A true and correct copy of pages 12, 13, 14, 15, 27, 31 and 33 of the application as filed, and a copy of the Notice of Allowability with the attached Examiner's Amendment, which support the Applicants' assertion of the error on the part of the Patent Office accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

Jenna M. Morrison
Patent Attorney
Registration No. 55,468
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

JMM/gld
Attachment: 1. Pages 12, 13, 14, 15, 27, 31 and 33 of the application
2. Notice of Allowability with the attached Examiner's Amendment,
2. Certificate of Correction in duplicate

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,998,040
APPLICATION NO. : 10/057,080
ISSUE DATE : February 14, 2006
INVENTOR(S) : Abdul Malik and James D. Hayes

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7, line 14 : " n-Octadecyidimethylmethoxysilane," should read -- n-Octadecyl dimethylmethoxysilane,--.

Column 7, line 14-15 :"Methyl-n-Octadecyidiethoxysilane," should read --Methyl-n-Octadecyl-diethoxysilane,--.

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Column 7, line 28-29: "3-mercaptopropylmethyidimethoxysilane" --3-mercaptopropylmethyl dimethoxysilane—.

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MAR - 6 2006

UNITED STATES PATENT AND TRADEMARK OFFICE

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Column 8, line 31-33: "3-mercaptopropylcyanopropydimethoxysilane, 3 mercaptopropyl octa-decyidiethoxysilane," should read --3-mercaptopropylcyanopropyldimethoxysilane, 3- mercapto-propyloctadecyldiethoxysilane,--.

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APR - 6 2006

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phenyl, cyclodextrins, crown ethers, Tetramethoxysilane, 3-(N-styrylmethyl-2-aminoethylamino)-propyltrimethoxysilane hydrochloride, *N*-tetradecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride, N(3-trimethoxysilylpropyl)-N-methyl-N,N-diallylammonium chloride, N-trimethoxysilylpropyltri-N-butylammonium bromide, N-trimethoxysilylpropyl-N,N,N-trimethylammonium chloride, Trimethoxysilylpropylthiouronium chloride, 3-[2-N-benzyaminoethylaminopropyl]trimethoxysilane hydrochloride, 1,4-Bis(hydroxy-dimethylsilyl)benzene, Bis(2-hydroxyethyl)-3-aminopropyltriethoxysilane, 1,4-bis(trimethoxysilylethyl)benzene, 2-Cyanoethyltrimethoxysilane, 2-Cyanoethyltriethoxysilane, (Cyanomethylphenethyl)trimethoxysilane, (Cyanomethylphenethyl)triethoxysilane, 3-Cyanopropyl-dimethylmethoxysilane, 3-Cyanopropyltriethoxysilane, 3-Cyanopropyltrimethoxysilane, *n*-Octadecyl-trimethoxysilane, *n*-Octadecyldimethylmethoxysilane, Methyl-*n*-Octadecyldiethoxysilane, Methyl-*n*-Octadecyldimethoxysilane, *n*-Octadecyltriethoxysilane, *n*-Dodecyl-triethoxysilane, *n*-Dodecyltrimethoxysilane, *n*-Octyltriethyoxysilane, *n*-Octyltrimethoxysilane, *n*-Ocyldi-isobutylmethoxysilane, *n*-ctylmethyldimethoxysilane, *n*-Hexyltriethoxysilane, *n*-isobutyltriethoxysilane, *n*-Propyltrimethoxysilane, Phenethyltrimethoxysilane, N-Phenylaminopropyltrimethoxysilane, Styrylethyl-trimethoxysilane, 3-(2,2,6,6-tetramethylpiperidine-4-oxy)-propyltriethoxysilane, N-(3-triethoxysilyl-propyl)acetyl-glycinamide, (3,3,3-trifluoropropyl)trimethoxysilane, (3,3,3-trifluoro-propyl)methyl-dimethoxysilane, 3-mercaptopropyltrimethoxysilane, 3-mercaptopropyltriethoxysilane, mercaptomethylmethyldiethoxysilane, 3-mercaptopropylmethyldimethoxysilane, 3-mercaptopropyloctadecyldimethoxysilane, 3-mercaptopropylloctyldimethoxysilane, 3-mercaptopropylcyanopropyldimethoxysilane, 3-mercaptopropyloctadecyldiethoxysilane, and any other similar precursor known to those of skill in the art. For instance, in one embodiment, the sol-gel precursor utilized is N-octadecyldimethyl[3- trimethoxysilyl)propyl]ammonium chloride (hereinafter "C_{18}-TMS"). When the sol-gel polymer gets bonded to the

capillary walls, the quaternary amine group in the precursor provides positive surface charge, while the octadecyl ligand in the surface coating coming from the precursor is capable of providing chromatographic interaction with the analytes. Thus, the sol-gel polymer forms an octadecylated sol-gel coating chemically bonded to the inner surface of the capillary. Thus, the resulting coating may contain residual silanol groups that need to be deactivated. In order to deactivate the stationary phase coating, a deactivating reagent such as phenyldimethysilane (PheDMS) is added to the sol-gel solution. The deactivation can take place during a thermal treatment step, which is carried out following the sol-gel coating procedure.

As described above, in addition to having a charged chemically-bonded stationary coating 14, the columns 10 of the present invention have sol-gel moieties that allow for the chemically bonding of the coating to the inner surface of the tube. The sol-gel moiety is made from various sol-gel precursors. In one embodiment of the present invention, the reagent system that is utilized for the fabrication of the coating includes two sol-gel precursors, a deactivation reagent, one or more solvents and a catalyst. For the purposes of the present invention, one of the sol-gel precursors contains a chromatographically active moiety selected from the group consisting of octadecyl, octyl, cyanopropyl, diol, biphenyl, phenyl, cyclodextrins, crown ethers and other moieties. Representative precursors include, but are not limited to: Tetramethoxysilane, 3-(N-styrylmethyl-2-aminoethylamino)-propyltrimethoxysilane hydrochloride, *N*-tetradecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride, N(3-trimethoxysilylpropyl)-N-methyl-N,N-diallylammonium chloride, N-trimethoxysilylpropyltri-N-butylammonium bromide, N-trimethoxysilylpropyl-N,N,N-trimethylammonium chloride, Trimethoxysilylpropylthiouronium chloride, 3-[2-N-benzyaminoethylaminopropyl]trimethoxysilane hydrochloride, 1,4-Bis(hydroxy-dimethylsilyl)benzene, Bis(2-hydroxyethyl)-3-aminopropyltriethoxysilane, 1,4-bis(trimethoxysilylethyl)benzene, 2-Cyanoethyltrimethoxysilane, 2-Cyanoethyltriethoxysilane,

(Cyanomethylphenethyl)trimethoxysilane, (Cyanomethylphenethyl)triethoxysilane, 3-Cyanopropyl-dimethylmethoxysilane, 3-Cyanopropyltriethoxysilane, 3-Cyanopropyltrimethoxysilane, *n*-Octadecyl-trimethoxysilane, *n*-Octadecyldimethylmethoxysilane, Methyl-*n*-Octadecyldiethoxysilane, Methyl-*n*-Octadecyldimethoxysilane, *n*-Octadecyltriethoxysilane, *n*-Dodecyl-triethoxysilane, *n*-Dodecyltrimethoxysilane, *n*-Octyltriethyoxysilane, *n*-Octyltrimethoxysilane, *n*-Ocyldi-isobutylmethoxysilane, *n*-ctylmethyldimethoxysilane, *n*-Hexyltriethoxysilane, *n*-isobutyltriethoxysilane, *n*-Propyltrimethoxysilane, Phenethyltrimethoxysilane, N-Phenylaminopropyltrimethoxysilane, Styrylethyl-trimethoxysilane, 3-(2,2,6,6-tetramethylpiperidine-4-oxy)-propyltriethoxysilane, N-(3-triethoxysilyl-propyl)acetyl-glycinamide, (3,3,3-trifluoropropyl)trimethoxysilane, (3,3,3-trifluoro-propyl)methyl-dimethoxysilane, 3-mercaptopropyltrimethoxysilane, 3-mercaptopropyltriethoxysilane, mercaptomethylmethyldiethoxysilane, 3-mercaptopropylmethyldimethoxysilane, 3-mercaptopropyloctadecyldimethoxysilane, 3-mercaptopropylloctyldimethoxysilane, 3-mercaptopropylcyanopropyldimethoxysilane, 3-mercaptopropyloctadecyldiethoxysilane, and any other similar precursor known to those of skill in the art.

As for the deactivation reagent, phenyldimethylsilane, and the catalyst, trifluoroacetic acid, they are selected for the preparation of the columns of the instant invention. However, any deactivation reagent and/or catalyst as known to those of ordinary skill in the art can be used.

As previously mentioned, one embodiment of the present invention utilizes the quaternary amine group of C_{18}-TMS. This group possesses a chromatographically favorable, bonded ODS moiety, in conjunction with three methoxy groups allowing for sol-gel reactivity. In addition, a positively charged nitrogen atom is present in the molecular structure of this reagent and provides

the positively charged capillary surface responsible for the reversed EOF in the columns during CEC operation. Thus, using C_{18}-TMS as a sol-gel precursor, a positively charged surface coating can be along the inner walls of the columns. The sol-gel created positively charged surface of the column of the present invention has a pI value of 8.5 and is responsible for the observed reversal of EOF in such sol-gel coated columns in CEC when the mobile-phase pH crosses this value.

In another embodiment of the present invention, a method of making the described column is provided. The sol-gel method of coating the open tubular column with a surface-bonded sol-gel stationary phase simply involves filling a capillary substrate such as fused-silica with a properly designed sol solution and maintaining the sol solution within the capillary for a short period of residence time (e.g., 15 to 30 minutes) to allow for chemical bonding of the growing sol-gel polymer to the capillary inner walls. Afterwards, expulsion of the unbounded surface part of the sol solution under an inert gas pressure occurs. Moreover, the coated capillary is further thermally treated and rinsed with a series of solvents before use.

In the presented sol-gel approach, a single step process is used to *in situ* create a chromatographically favorable stationary-phase coating chemically bonded to the inner walls of the fused-silica capillary. One associated advantage to this particular technique originates from the use of a selectively chosen, commercially available sol-gel precursor, C_{18}-TMS. The chemical structures of this reagent, and other ingredients used for the fabrication of the sol-gel coatings are given in Table 1. As depicted in Table 1, the chemical architecture of C_{18}-TMS elegantly combines three important features: (1) three methoxysilyl groups that can undergo sol-gel reactions and *in situ* create a chemically bonded stationary phase in the form of a surface coating; (2) the octadecyl chain that remains chemically bonded to the sol-gel surface coating as a pendant group to provide the essential chromatographic interactions with the solute molecules; (3)

the mobile phase to interact with the stationary phase. For this reason, slower mobile-phase mass transfer that is typical of larger analytes adversely affect the separation efficiency at high mobile-phase velocities. Indeed, fluoranthene and pyrene show a slight increase in plate heights with an increase in mobile-phase velocity beyond.

The OT-CEC separation of a probe mixture of aldehydes and ketones obtained on a PheDMS-deactivated ODS coated sol-gel column is illustrated in Figure 7. Unlike the PAHs, these solutes are more polar (i.e., less hydrophobic). Successful separation of this test mixture provides substantial evidence in favor of the viability of 25μm-i.d. sol-gel coated ODS columns for OT-CEC.

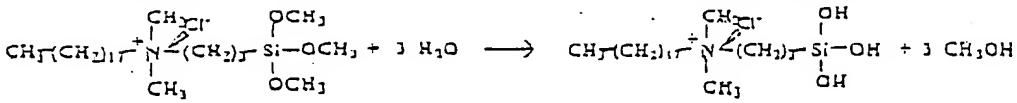
For this separation, the highest column efficiency is 404,000 theoretical plates/m for thiourea using a mobile phase containing 60% acetonitrile and 40% tmM Tris-HCl (Table 3).

As for Figure 8, it illustrates an OT-CEC separation of a test mixture of benzene derivatives on a PheDMS-deactivated sol-gel ODS column. In this analysis, the obtained separation efficiencies ranging between 204,000 theoretical plates/m (for butylbenzene) and 384,00 plates/m (for thiourea) are achieved on a 64 cm x 25 μm i.d. PheDMS-deactivated sol-gel C_{18} coated column. In all instances, the achieved efficiencies are comparable to those reported previously for sol-gel C_8 columns in OT-CEC by Guo and Colon (Guo et al.), who used open-tubular columns of much reduced internal diameter (e.g. 10-13 μm i.d.).

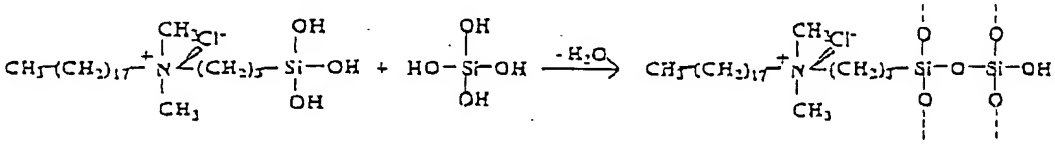
Figure 9 represents the dependence of EOF on the pH of the buffer used in the mobile phase to run a PheDMS-deactivated sol-gel C_{18} coated OT-CEC column. A set of three runs are conducted for each mobile-phase pH. A series of mobile phases consisting of 50:50 (v/v) ACN/5 mM Tris-HCl is prepared using Tris-HCl solutions with pH values in the range of 2.34 and 9.91. Thiourea is

Tock, P. et al. Chromatographia, 24, 617 (1987).
Tsuda, T. et al. J. Chromatogr, 214, 283 (1981).
Tsuda, T. et al. J. Chromatogr, 248, 241 (1982).
Van Berkel, et al. Chromatogr, 449, 345 (1990).
Van Berkel, et al. Chromatographia, 24, 739 (1987).
Wang, D., et al. Anal Chem., 69, 4563 (1997).
Yang, C. et al. Electrophoresis., 19, 2278 (1998).
Zhang, Y. et al. J. Liq. Chromatogr., 18, 3373 (1995).

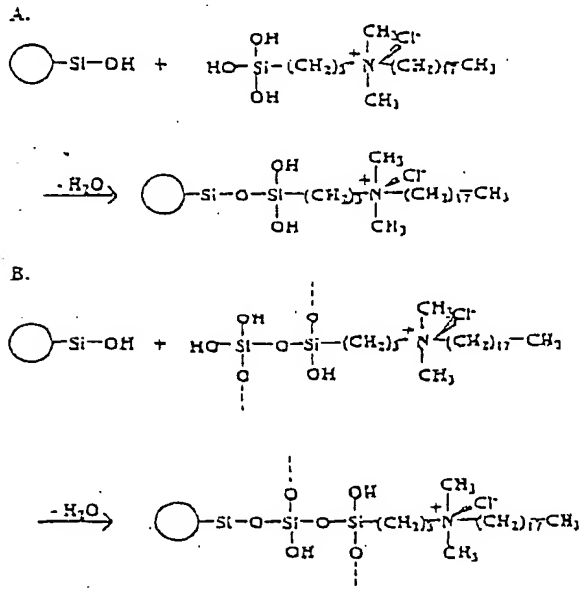
Scheme 1. Complete Hydrolysis of *N*-Octadecyldimethyl[3-(trihydroxysilyl)propyl]ammonium Chloride



Scheme 2. Condensation of Tetrahydroxysilane with *N*-Octadecyldimethyl[3-(trihydroxysilyl)propyl]ammonium Chloride

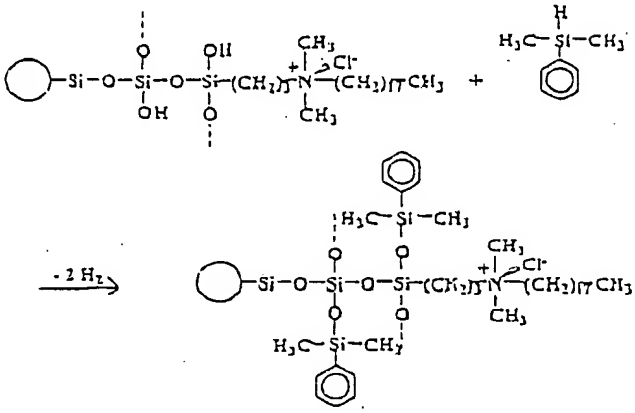


Scheme 3. Bonding of the Sol–Gel ODS Coating with the Fused-Silica Surface[a]



[a](A) Bonding of *N*-Octadecyldimethyl[3-(trihydroxysilyl)propyl]ammonium chloride with the fused-silica surface. (B) Bonding of the product of the condensation reaction of tetrahydroxysilane with *N*-octadecyldimethyl[3-(trihydroxysilyl)propyl]ammonium chloride with the fused-silica surface.

Scheme 4. Deactivation of the Sol–Gel Mediated Fused-Silica Coated Surface with Phenyldimethylsilane (PheDMS)



Notice of Allowability

Application No.	Applicant(s)	
10/057,080	MALIK ET AL.	
Examiner	**Art Unit**	
Ernest G. Therkorn	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *July 5, 2005*.
2. ☒ The allowed claim(s) is/are *1-13 and 23-25*.
3. ☒ The drawings filed on *24 January 2002* are accepted by the Examiner.

COPY

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In claim 1, line 3, after "thereon", - - that permits effective controlling of electroosmotic flow in the column - - has been inserted.

Claims 14-22, drawn to non-elected inventions, have been cancelled.

The following claims have been added:

- - 23. The open tubular capillary electrochromatography column according to claim 1, wherein said effective controlling of electroosmotic flow on the column comprises adjusting the pH of the mobile phase.

24. The open tubular capillary electrochromatography column according to claim 1, wherein said coating is defined as a sol-gel polymer including a positively charged moiety and chromatographic ligand; and wherein said effective controlling of electroosmotic flow on the column comprises adjusting the concentration of the positively charged moiety.

25. The open tubular capillary electrochromatography column according to claim 1, wherein said coating is defined as a sol-gel polymer including a negatively charged moiety and chromatographic ligand; and wherein said effective controlling of electroosmotic flow on the column comprises adjusting the concentration of the negatively charged moiety. - -

Authorization for this examiner's amendment was given in a telephone interview with Jenna M. Morrison on July 25, 2005.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernest G. Therkorn
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Primary Examiner
Art Unit 1723

EGT
July 25, 2005